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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,580	11/14/2003	Paul Wentworth	1361.027US1	1792

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,580	WENTWORTH ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20 are drawn to an anti-microbial composition, classified in class 424, subclass 53.

   II. Claims 21-39 are drawn to a method of treating a microbial infection in a mammal, classified in class 424, subclass 184.1.

   III. Claims 40-47 are drawn to a method of generating a reactive oxygen species, classified in class 436, subclass 512.

2. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of group I can be practiced with a materially different process such as with a method for targeting cancer cells for oxidant-induced lysis. Thus the inventions have been shown to be distinct since the product as claimed can be used in a materially different process of using that product.

Searching the inventions of groups I and II together would impose serious search burden. The inventions of groups I and II have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the

composition and the method of treating a microbial infection are not coextensive. Group I encompasses a composition, and therefore is not required for the search of group II. Furthermore, the search for group II would require a text search for a method of treatment comprising determining the type of microbe or microbial associated disease and would not necessarily encompass a search for the composition. Moreover, even if the composition were known, the method of treating a microbial infection in a mammal may be novel and unobvious in view of the preamble or active steps.

(ii) Inventions II and III are related as distinct methods because they are different methods with different method steps; reagents; functions and each method results in different final outcomes. First, the instant specification does not disclose that these methods would be used together. The methods are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs its function using structurally and functionally divergent material. For instance, the method of treating a microbial infection in a mammal, is not necessary to practice the method of generating a reactive oxygen species. In this case, group III is separate and distinct, from group II, since group III comprising contacting the microbe with an antibody and a source of singlet oxygen. Furthermore, only group II treats a microbial infection by administering to the mammal an anti-microbial composition consisting essentially of an antibody that can bind to a microbe and a pharmaceutically acceptable carrier. This method is separate and distinct from the other method. Therefore, each method is divergent with respect to the amounts

of reagents used and their associated steps. For these reasons the inventions of groups II and III are patentably distinct.

Furthermore, searching the inventions of groups II and III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method of treating a microbial infection in a mammal, requires a different search, than a method of generating a reactive oxygen species. Thus, a search drawn to a treatment method, is not necessary for a determination of novelty and unobviousness of the method of group III which comprises contacting the microbe with an antibody and a source of singlet oxygen. Furthermore, the method of group II may be known even if the method of group III is novel. In addition, the technical literature search for the method of group II and the method of groups III are not coextensive, since, for instance, the method group II may be characterized in the technical literature prior to discovery of the method of group III.

(iii) Inventions I and III are unrelated because this product and method are not used or otherwise involved in any of the above recited methods. The method of group III does not make or use the product of group I. For these reasons the inventions I and III are patentably distinct.

3. The inventions of Groups I-III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-III together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

5. This application contains claims from Group II which are directed to the following patentably distinct species of the claimed invention:

Species A: wherein the microbe is *Aeromonas* spp., *Bacillus* spp., *Bacteroides* spp., *Campylobacter* spp., *Clostridium* spp., *Enterobacter* spp., *Enterococcus* spp., *Escherichia* spp., *Gastrospirillum* spp., *Helicobacter* spp., *Klebsiella* spp., *Salmonella* spp., *Shigella* spp., *Staphylococcus* spp., *Pseudomonas* spp., *Vibrio* spp., or *Yersinia* spp.

Species B: wherein the microbe is associated with a staph infection, typhus, food poisoning, bascillary dysentery, pneumonia, cholera, an ulcer, diarrhea, hemorrhagic colitis, hemolytic uremic syndrome, or thrombotic thrombocytopenic purpura.

Species C: wherein the microbe is a viroid or prion.

Species D: wherein the microbe is a hepatitis A virus, hepatitis B virus, hepatitis C virus, human immunodeficiency virus, poxvirus, herpes virus, adenovirus, papovavirus, parvovirus, reovirus, orbivirus, picomavirus, rotavirus, alphavinzs, rubivirus, influenza virus, orbivirus, picornavirus, rotavirus, alphavirus, rubivirus, influenza virus type A, influenza virus type B, flavivirus, coronavirus, paramyxovirus, morbillivirus, pneumovirus, rhabdovirus, lyssavirus, orthmyxovirus, bunyavirus, phlebovirus, nairovirus, hepadnavirus, arenavirus, retrovirus, enterovirus, rhinovirus or filovirus.

The bacteria of species A are unicellular prokaryotic microorganisms which generally possess rigid cell walls, multiply by cell division, and exhibit three principal forms: round or coccal, rodlike or bacillary, and spiral or spirochetal. They can also be classified by whether or not they stain (based on the structure of their cell walls) with crystal violet dye: gram-negative or gram-positive.The viroids of species C are a group of pathogens comprising the smallest known agents of infectious disease. The viroids are unencapsulated and are capable of replicating autonomously in susceptible cells. Positively identified viroids composed of single-stranded RNA have been isolated from higher plants, but the existence of DNA viroids pathogenic to animals is suspected. Prions are small proteinaceous infectious particles which resist inactivation by procedures that modify nucleic acids and contain an abnormal isoform of a cellular protein which is a major and necessary component. The species of group D is drawn to viruses which are minute infectious agents whose genomes are composed of DNA or

RNA, but not both. They are characterized by a lack of independent metabolism and the inability to replicate outside living host cells. Thus the species are structurally distinct microbes. And these microbes as determined by their different structure and associated functions are patentably distinct, each from the other. Moreover, one microbe is not required to practice the invention with another. Each microbe comprises separate and distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

6. Therefore it is noted that: If applicant elects species A, then claims 29-30 and 32-34 will be examined; if applicant elects species B, then claims 31 will be examined; if applicant elects species C claims 35 and 38 will be examined, and if applicant elects species D, then claims 35 and either elected claim 36 or 37 will be examined. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 21-28 and 39 are generic.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 26, 2005